July 5, 2022

# Anebulo Pharmaceuticals Announces Positive Topline Data for ANEB-001 from a Phase 2 Clinical Trial for Acute Cannabinoid Intoxication

- **Study Met Primary Endpoint VAS Feeling High (p < 0.0001)**
- **Statistically Significant and Sustained Reductions in Key THC-Related CNS Symptoms**
- **Conference Call 8:30am Eastern Time Today**

AUSTIN, Texas--(BUSINESS WIRE)-- **Anebulo Pharmaceuticals, Inc.** (Nasdaq: ANEB), a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication (ACI) and substance abuse disorders (the "Company" or "Anebulo"), today announced positive topline data from Part A of an ongoing Phase 2 clinical trial evaluating the potential of ANEB-001 to treat ACI. Part A was a 60 subject randomized, double-blind, placebo-controlled trial designed to evaluate the effectiveness of a single dose of ANEB-001 in treating healthy subjects challenged with delta-9-tetrahydrocannabinol, better known as THC, the primary psychoactive constituent of cannabis. These data demonstrated a highly statistically significant reduction in key symptoms of ACI, with only 10% of subjects in the 50 mg ANEB-001 group and 30% in the 100 mg group reporting feeling high compared to 75% of subjects in the placebo group ($p < 0.001$). ANEB-001 was well tolerated in these healthy volunteers. Preliminary safety information showed all adverse events were mild and transient, except in the case of one subject in the 50 mg ANEB-001 group who experienced moderate nausea and vomiting.

"We believe this proof-of-concept trial demonstrates ANEB-001's potential to reverse the symptoms of ACI for many of the five thousand cannabinoid intoxicated individuals visiting our emergency departments in the United States on a daily basis," said Simon Allen, Chief Executive Officer of Anebulo. "We believe marijuana legalization and greater consumer access to cheaper and higher potency THC products will continue to increase the incidence and severity of emergency department visits related to cannabinoid intoxication. With no FDA approved therapy, individuals intoxicated with cannabinoids have few treatment options and may require expensive follow-on interventions for neuropsychiatric complications such as anxiety and acute psychosis. ANEB-001 has the potential to mitigate these unfortunate circumstances and reduce their burden on individuals, society, and our healthcare system."

The study was conducted at the Centre for Human Drug Research (CHDR) in the Netherlands and enrolled 60 healthy adult occasional cannabis users randomized to three treatment arms of 20 subjects per arm. All subjects were challenged with a single oral dose of 10.5 mg THC and then treated with single oral doses of 50 mg ANEB-001, 100 mg ANEB-001, or placebo. Subjects were monitored for 24 hours to assess safety, tolerability, and pharmacokinetics, and repeatedly tested to determine potential effects on endpoints related

to ACI symptoms. The tests also included a series of validated measures of subjective CNS symptoms using visual analog scale (VAS) assessments, as well as objective measures of intoxication. Subjects challenged with THC and treated with placebo showed substantial CNS effects including feeling high, decreased alertness, increased body sway, and increased heart rate. Compared to placebo, treatment of subjects with ANEB-001 led to a significant, robust, and sustained reduction in the VAS feeling high score ($p < 0.0001$ at both dose levels) and improvement in the VAS alertness scale ($p < 0.01$). In addition, the proportion of subjects reporting feeling high on the VAS was significantly reduced by ANEB-001 ($p < 0.001$). Although THC-induced effects on body sway and heart rate in this study were small, there was also a trend towards statistical improvement of these parameters with ANEB-001 treatment compared to placebo. The 50 mg and 100 mg doses had similar results, suggesting that lower doses should be explored. Pharmacokinetic data are pending and additional analyses of Part A data, including pharmacokinetic/pharmacodynamic (PK/PD) correlations, are planned.

“The number of individuals with cannabinoid related intoxication visiting our emergency departments is clearly on the rise,” said Dr. Andrew Monte M.D., Ph.D., Professor of Emergency Medicine & Medical Toxicology, University of Colorado Denver-Anschutz Medical Center. “Patients are coming from multiple settings including first-time users taking small doses of THC, adults and children inadvertently ingesting powerful THC gummies, and regular users unintentionally overdosing on new and more powerful THC products. Introducing an effective cannabinoid antidote into our treatment options would represent a significant improvement in how we can manage these patients”

Based on the encouraging data from Part A, the Company plans to initiate Part B of the study at CHDR by the end of third quarter 2022 to evaluate lower doses of ANEB-001. Anebulo is currently collaborating with the Model-Informed Drug Development (MIDD) group at FDA to develop a PK/PD model that will potentially allow prediction of optimal doses for treatment of ACI subjects. Preparations are ongoing for an observational study in ACI subjects in the emergency department setting to further support the PK/PD model and ANEB-001 development. Submission of an Investigational New Drug application (IND) for ANEB-001 to initiate U.S. trials is anticipated by the end of 2022.

**Conference Call and Webcast**

Anebulo will host a conference call and webcast today, July 5, 2022, at 8:30 am Eastern Time to discuss topline data from the ANEB-001 Phase 2 Part A Proof-of-Concept clinical trial. To access the audio webcast with slides, please visit the “Events & Presentations” page in the Investors & Media section of the Company’s website at https://ir.anebulo.com/company-information/presentations. The call can also be accessed by dialing (877) 407-8815 (domestic) or +1 (201) 689-8025 (international) with conference ID 13731361.

For those unable to participate in the conference call or webcast, a replay will be available on the Company’s website.

**About Visual Analogue Scale (VAS)**

VAS is a tool used to help rate the intensity of certain sensations and feelings, such as feeling high. The visual analog scale is typically a straight line with one end meaning not high

and the other end meaning extremely high. A patient marks a point on the line that matches how high they feel.

**About Acute Cannabinoid Intoxication (ACI)**

Symptoms of ACI can include increased somnolence, impaired cognition and perception, disorientation, anxiety, and acute psychosis. According to DSM-5, a diagnosis of cannabinoid intoxication should include recent history of cannabinoid use, clinically considerable behavioral or psychological changes, such as euphoria, impaired judgment and motor skills, which have taken place since cannabinoid exposure.

**About CHDR**

The Centre for Human Drug Research (CHDR) is an independent institute that specializes in cutting-edge early-stage clinical drug research. Combining innovative methods and technologies, state-of-the-art facilities, and talented, motivated researchers helps CHDR maximize their clients' success. In addition, CHDR places the highest priority on their subjects' comfort and safety, and they play an active role in helping educate the medical and clinical research communities.

**About Anebulo Pharmaceuticals, Inc.**

Anebulo Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication and substance abuse disorder. Its lead product candidate, ANEB-001, is currently in a Phase 2 clinical trial (www.clinicaltrials.gov/ct2/show/NCT05282797) to evaluate its utility in reversing the negative effects of acute cannabinoid intoxication within one hour of administration. ANEB-001 is a competitive antagonist at the human cannabinoid receptor type 1 (CB1). For further information about Anebulo, please visit www.anebulo.com.

**Forward-Looking Statements**

This press release contains forward-looking statements as defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements, along with terms such as "anticipate," "expect," "intend," "may," "will," "should" and other comparable terms, involve risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. Those statements include statements regarding the intent, belief or current expectations of Anebulo and members of its management, as well as the assumptions on which such statements are based. These forward-looking statements include, but are not limited to, those regarding: ANEB-001's potential to reverse the symptoms of ACI for many of the five thousand cannabinoid intoxicated individuals visiting our emergency departments in the United States on a daily basis; the belief that marijuana legalization and greater access to cheaper and higher potency THC products will continue to increase the incidence and severity of emergency department visits related to cannabinoid intoxication; the possibility that individuals intoxicated with cannabinoids may require expensive follow-on interventions for neuropsychiatric complications such as anxiety and acute psychosis; ANEB-001's potential to mitigate these unfortunate circumstances and reduce their burden on individuals, society, and our healthcare system; the Company's plans to conduct additional analysis of Part A data, including PK/PD correlations; the Company's plans to

initiate Part B of the study and the design, progress and expected timing thereof; the Company's plans to develop a PK/PD model and the potential thereof to predict optimal doses for treatment of ACI subjects; the Company's plans with respect to an observational study in ACI subjects in the emergency department; and the Company's intention to submit an IND and the expected timing thereof. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and are subject to a number of risks, uncertainties and assumptions, including, but not limited to: there is no guarantee that the Company's planned IND for ANEB-001 will be cleared by the FDA; initial results from clinical studies are not necessarily indicative of results that may be observed in the future; clinical trial site challenges that may impact the expected timing of the Company's ongoing clinical trials, including challenges related to the ongoing COVID-19 pandemic; the timing and success of clinical trials and potential safety and other complications thereof; any negative effects on the Company's business, commercialization and product development plans caused by or associated with COVID-19 or geopolitical issues; and those described in Anebulo's most recent annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on September 22, 2021 and in other periodic reports filed with the SEC, and that actual results may differ materially from those contemplated by such forward-looking statements. Except as required by federal securities law, Anebulo undertakes no obligation to update or revise forward-looking statements to reflect changed conditions.

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